

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2015.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-557

Trade Name: Tiletamine-Zolazepam
Pioneer: Telazol®
Ingredients: Tiletamine hydrochloride and Zolazepam Hydrochloride
Sponsor: Putney, Inc.
Approval Date: March 26, 2015
Status: Rx
Route: Intramuscular injection
Species: Cats and dogs
Drug Form: Injectable Solution
Concentration: The addition of 5 mL of sterile water for injection results in each one mL containing 50 mg tiletamine and 50 mg zolazepam.
Indications: Tiletamine-Zolazepam is indicated in cats for restraint or for anesthesia combined with muscle relaxation and in dogs for restraint and minor procedures of short duration (30 min. avg.) requiring mild to moderate analgesia.
Exclusivity: N/A
Patent: N/A

ANADA Number: 200-578

Trade Name: Carprofen Flavored Tablets
Pioneer: Rimadyl® Caplets
Ingredients: Carprofen
Sponsor: Belcher Pharmaceuticals, LLC
Approval Date: March 25, 2015
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablets
Concentration: 25 mg, 75 mg, and 100 mg
Indications: For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.
Exclusivity: N/A
Patent: N/A

Sponsor Change

NADA Numbers: 140-883, 141-188

Previous: Bayer HealthCare LLC
New Sponsor: Merial Ltd.
Drug Labeler Code: 050604

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Patent Additions

NADA Number: 141-036

Patent number: 6,890,929
Expiration Date: June 17, 2019

Patent number: 7,687,507
Expiration Date: June 17, 2019

Patent number: 8,133,899
Expiration Date: April 9, 2030